CRA Training for Entry Level
March, 25-26 2021

A Clinical Research Associate (CRA) is the person responsible for ensuring that the clinical trial is conducted following Good Clinical Practice (GCP) protocol and applicable legislation.

The Clinical Research Associate (CRA) Training Program will increase your knowledge and skills required for working and keeping up with the latest developments in the clinical research arena as a fully qualified CRA.
The Module 1 – CRA Training for Entry Level is dedicated to junior Clinical Research Associates (CRA), Clinical Research Assistants (CTA), young professionals willing to enter in the clinical trials field as monitors, such as physicians, pharmacists, residents, students, biologists, biochemists.

The participants to Module 1 – CRA Training for Entry Level will benefit of 15% discount to Module 2 – CRA Training for Advanced Level.

Clinical Research Associate (CRA) Training Program
Module 1 - CRA training for Entry Level

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Scope: Understanding scope and execution of monitoring following ICH E6 (R2) §5.18

Language: English

Price: 350 Euro / 1700 Lei (no VAT refund)

Location: Radisson Blu Bucharest Hotel

Speaker:

DR. CATALINA SARBU Head of the CRO Association in Romania (ACCSCR)
Director Clinical Operations Parexel International Romania

- General Manager Business Administration & Director Clinical Operations at Parexel
- 2004-GMBA and Director Clinical Operations–PAREXEL International Romania S.R.L.
- 2000–Director of the Romanian Representative office of PAREXEL Nederland BV
- General Practitioner –Center of Hematology, Ploiesti, Romania
- Saint Antoine University, Paris, France - Hematology and Blood Transfusion, 1-year courses
- University of Medicine and Pharmacy, Bucharest, Romania -Medical Doctor Degree

AGENDA - 2 days

DAY 1 - 25th March 2021

8:30 – 9:30 REGISTRATION

9:30 – 11:00 GENERAL OVERVIEW OF CLINICAL TRIALS

- A short history of Good Clinical Practice (GCP) guidelines
- Drug development and various types of clinical trials
- The Principles of ICH GCP (International Council for Harmonisation guidelines for Good Clinical Practice)
- Declaration of Helsinki
- Running a clinical trial - the steps

11:00 – 11:30 COFFEE BREAK

11:30 – 13:00 RESPONSIBILITIES

- Investigators' responsibilities
- Monitoring responsibilities and limits
- Sponsor's responsibilities

13:00 – 14:00 LUNCH

14:00 – 15:30 ESSENTIAL DOCUMENTS IN CLINICAL TRIALS

- The significance of various documents in clinical trials
- The patient file and other source documents in clinical trials (practical approach)
- Medical history and physical examination
- Concomitant medical conditions and related medication
- Non-clinical investigations in clinical trials
- ALCOAC principles in practice

15:30 – 16:00 COFFEE BREAK

16:00 – 17:30 INFORMED CONSENT

- The Informed Consent Procedure
- Legal representative, witness

DAY 2 - 26th March 2021

8:30 – 9:30 REGISTRATION

9:30 – 11:00 SAFETY REPORTING IN CLINICAL TRIALS

- Investigators to sponsor
- Sponsor to authorities
- The unblinding procedure

11:00 – 11:30 COFFEE BREAK

11:30 – 13:00 AUDITS AND INSPECTIONS

- Audits and inspections including frequent audit findings
- FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), sponsor inspections

13:00 – 14:00 LUNCH

14:00 – 15:30 MISCELLANEOUS

- Data management, statistical analysis
- Archiving of clinical trials at the site (ISF) and sponsor (TMF)
- Site contracts and investigators/institutions payment
- Subcontracted vendors

15:30 – 16:00 COFFEE BREAK

16:00 – 17:00 TEST

- Test (multiple choices)

The **Participation Certificates** will be available to be downloaded from the participants' accounts on www.avantyo.com.
Download here the info brochure of the training.

Discounts are offered for companies sending over 3 participants.
For more information please contact us
at info@avantyo.com, diana.lupu@gmail.com or 0726 840 456.

Come back soon for more information about the Module 2 - CRA Training Advanced Level!

If you would like to be placed on a waiting list for the next course or you need something else, please let us know at info@avantyo.com. Don't forget to mention your specific education needs in clinical trials.
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